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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CEPHALON, INC. Plaintiff, v. SUN PHARMACEUTICALS, LTD., & CARACO PHARMACEUTICAL LABORATORIES LTD., Defendants.	Case No. 11-5474(FLW) **OPINION**

WOLFSON, United States District Judge:

In this case, Plaintiff Cephalon, Inc. ("Plaintiff" or "Cephalon") has sued Sun Pharmaceuticals, Ltd. and Caraco Pharmaceutical Laboratories, Ltd. (collectively "Defendants" or "Sun") for patent infringement in violation of Title 35 of the United States Code, and Sun has filed a counterclaim against Cephalon for a declaratory judgment that the patent at issue is invalid and that Sun does not infringe the patent at issue. The patent at issue, United States Patent No. 5,958,951 (the "'951 patent"), relates to the pharmaceutical composition of anhydrous tiagabine hydrochloride ("HCl") in the drug marketed by Cephalon under the name "Gabatril" and used to treat epilepsy. Sun filed an Abbreviated New Drug Application ("ANDA") for approval to market a generic version of Gabatril prior to the expiration of the '951 patent. Presently before the Court is Cephalon's motion to enjoin Sun from distributing its generic version of tiagabine HCl tablets (the "Sun Tablets"). There are two issues before the Court on this motion for a preliminary injunction: (1) whether Plaintiff has met its burden of demonstrating a likelihood of success on the issue of infringement; and (2) whether the

Defendants have met their burden of raising a substantial question of the patent's validity.

The Court held evidentiary hearings spanning two days with an expert on each side testifying as to the issue of infringement and a Sun expert testifying as to the issue of invalidity. With regard to infringement, Cephalon contends that its expert has demonstrated that the Sun Tablets' Active Pharmaceutical Ingredient ("API") matches the anhydrous tiagabine HCl form claimed by the '951 patent. Thus, Cephalon argues, the Sun Tablets infringe the '951 patent when they are offered for sale in the United States. In response, Sun claims that Cephalon's evidence is insufficient to demonstrate a likelihood of success on the infringement claim. With regard to invalidity, Sun argues that a prior art publication teaches or enables the claims in the '951 patent, and thus the prior art inherently anticipates the '951 patent, rendering it invalid.

After careful consideration of all the parties' written submissions and evidence, the Court concludes that Plaintiff has not met its burden of demonstrating a likelihood of success on the merits of its infringement claim. Additionally, the Court concludes that Defendants have raised a substantial question concerning the validity of the '951 patent, which Plaintiff has failed to demonstrate lacks substantial merit. Accordingly, the Court denies Plaintiff's motion for preliminary injunctive relief.

I. PROCEDURAL HISTORY

In the interest of clarity, the Court begins with the procedural history of this case before setting out the relevant facts. Cephalon filed its first Complaint against defendants Sun Pharmaceutical Industries, Ltd., and Sun Pharmaceutical Industries, Inc., on September 21, 2011. Shortly thereafter, Cephalon filed a motion for a temporary restraining order and preliminary injunction. Sun Pharmaceutical Industries, Ltd. filed a motion to dismiss the Complaint for insufficient service of process pursuant to Fed. R. Civ. P. 12(b)(5). Sun Pharmaceutical

Industries, Inc., also filed a motion to dismiss the Complaint for lack of jurisdiction and failure to state a claim. Both Sun defendants additionally filed a motion to dismiss Cephalon's motion for a temporary restraining order and preliminary injunction. On December 5, 2011, the Court issued an order that (i) dismissed, upon consent, Sun Pharmaceuticals Industries, Inc. from the action, (ii) quashed service on Sun Pharmaceuticals, Ltd., as being insufficient under the Hague Convention, (iii) dismissed Cephalon's motion for a temporary restraining order and preliminary injunction, and (iv) granted Cephalon leave to amend its Complaint. On the same day, Cephalon filed its first Amended Complaint naming the current Defendants, Sun Pharmaceutical Industries, Ltd. and Caraco Pharmaceutical Laboratories, Ltd. Defendants have not made any further motions regarding service of process or jurisdiction.

Defendants filed an Answer to the Amended Complaint, and asserted a Counter-Claim seeking a declaratory judgment that the Sun Tablets do not infringe the '951 patent and that the '951 patent is invalid. After filing an Answer to the Counter-Claim, Cephalon filed the instant motion for a temporary restraining order and preliminary injunction. On February 7, 2012, the Court issued an order denying Cephalon's request for a temporary restraining order, concluding that on the record as it existed on the date of the order, Cephalon had not shown a likelihood of success on the merits of its infringement claim. The Court reserved decision on Cephalon's request for a preliminary injunction, and the parties proceeded with further expert declarations and discovery.

In accordance with a scheduling order, the parties submitted supplemental papers regarding Cephalon's motion for a preliminary injunction. The Court additionally held two days of hearings during which it received expert testimony, exhibits, and argument. At the November 15, 2012, hearing ("the November hearing"), Cephalon presented its expert, Dr. David E. Bugay,

and Sun presented its expert, Dr. Peter W. Stephens, both on the issue of infringement. The parties also introduced into evidence exhibits and made argument on that issue at the hearing, and thereafter submitted written summations. At the December 4, 2012 hearing ("the December hearing"), Sun presented its expert, Dr. Kevin J. Roberts, exhibits, and argument on the issue of invalidity. Cephalon did not present an expert on this issue, relying on its cross-examination of Dr. Roberts, exhibits, and argument.

II. FACTUAL OVERVIEW

The following relevant facts are undisputed unless otherwise noted. Additional facts will be set forth as necessary, as well as any findings of fact necessary to decide Cephalon's motion for a preliminary injunction.

A. Tiagabine HCl and Crystalline Polymorphs Generally

Tiagabine HCl is a pharmaceutical compound that is the subject of several patents. The compound can occur in many different forms, including in both solid and amorphous forms. See generally Dkt. No. 49 at ¶ 19 (Bugay 1st Decl.); Dec. Hearing at 12 (Roberts Testimony). The solid form for tiagabine HCl itself may occur in a variety of crystalline forms, having the same chemical composition but different crystalline structures. Dkt. No. 49 at ¶ 19. These different crystalline forms are commonly characterized and referred to as "polymorphs." Id.; see also Nov. Hearing at 164 (Stephens testimony) ("[T]iagabine HCl is a very heavily polymorphic material. There are a large number of different crystal forms of tiagabine HCl . . . ."). Thus, as described in more detail infra, infringement claims involving tiagabine HCl will often require a determination of the specific polymorph of the alleged infringing form.

A method commonly used to indentify a specific polymorph in a given sample of tiagabine HCl is x-ray powder diffraction ("XRPD") analysis. See generally Dkt. No. 49 at ¶ 20;

Dec. Hearing at 16-17 (Roberts testimony). Subjecting a sample of tiagabine HCl to XRPD generates a diffraction pattern. See Dec. Hearing at 17. Contained within this pattern is a series of XRPD "peaks" that aid in identifying the polymorphic composition of that sample. Id.; see also Nov. Hearing at 56-60 (Bugay Testimony). All parties and their respective experts in this case rely solely on XRPD as the method for identifying the polymorph claimed in the '951 patent and the polymorph(s) present in the Sun API and the Sun Tablets.

B. The '951 Patent[1]

Cephalon is the owner of the '951 patent and holder of a New Drug Application for Gabatril tablets in 2 mg, 4 mg, 12 mg, and 16 mg dosage forms containing anhydrous tiagabine HCl. Amend. Compl. at ¶ 4. Gabatril is a prescription drug used as an anti-epilepsy agent. Id. at ¶¶ 5-6. The '951 patent was issued on September 28, 1999, to Novo Nordisk A/S ("Novo"), following an application filed on June 10, 1997; it was later assigned to Cephalon on August 29, 2011. Dkt. No. 8-1, 8-7. The '951 patent includes seven claims, three of which are relevant to this matter:

> 1. Anhydrous crystalline R(-)-N-)4,4di(3-methylthien-2yl)but-3-enyl)nipecotic acid hydrochloride having substantially the following X-ray powder diffraction peaks obtained with KBr: 6.4, 11.3, 13.0, 13.9, 15.0, 18.7, 19.4, 22.5 and 23.7.
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> 2. Anhydrous crystalline R(-)-N-)4,4di(3-methylthien-2yl)but-3-enyl)nipecotic acid hydrochloride substantially free of bound organic solvent having substantially the following X-ray powder diffraction peaks obtained with KBr: 6.4, 11.3, 13.0, 13.9, 15.0, 18.7, 19.4, 22.5 and 23.7.
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> 4. A pharmaceutical composition comprising a therapeutically effective amount of a crystalline salt according to claim 1 together with a pharmaceutically acceptable carrier or diluent.

As discussed in more detail infra, the parties' arguments turn on the XRPD peaks in

[1] The '951 patent is attached to Cephalon's initial moving papers as Exhibit A to Declaration of Elina Slavin. Dkt. 8-1.

claim 1 and claim 2 of the '951 patent. Thus, for the purposes of the instant motion, the Court centers its analysis on the nine XRPD peak values: 6.4, 11.3, 13.0, 13.9, 15.0, 18.7, 19.4, 22.5, and 23.7. Further references to the claims of the '951 patent mean these nine XRPD peaks unless otherwise noted.

The specification of the '951 patent references two other patents. U.S. Patent No. 5,010,090 ("the '090 patent") "discloses a class of novel compounds . . . [that] are valuable for therapeutic use in the treatment of epilepsy." Dkt. No. 8-1. U.S. Patent No. 5,354,760 ("the '760 patent") discloses tiagabine hydrochloride in its monohydrate form. Dkt. No. 8-1. These prior patents are relevant to the instant matter insofar as they relate to tiagabine HCl. Additionally, the '951 patent abstract also discloses a reference to the following prior art publication: "McGraw, et al. 'The identification and characterization of polymorphism in tiagabine HCl bulk drug.' Derwent abst 95-05633, 1994." No further reference to this publication is found in the '951 patent. However, in the patent prosecution history of the '951 patent, Novo distinguished the teachings of the McGraw abstract from the claims of the '951 patent, explaining that "McGraw et al. teach that tiagabine can crystallize into two distinct polymorphic forms, namely a monohydrate crystal and an anhydrous crystal, but do not teach or suggest any x-ray diffraction pattern for their anhydrous form." Dkt. No. 8-6 ('951 patent history) (Letter from Carol E. Rozek, Novo Nordisk of North America, July 13, 1998 at 5).

Several other aspects of the patent prosecution history are relevant to this matter. The original patent application for the '951 patent was rejected because it did not include any peak values for the X-ray powder diffraction ("XRPD") pattern or peaks. See Dkt. No. 8-5 ('951 patent history) (USPTO Office Action Summary, Apr. 15, 1998). The USPTO Examiner ("Examiner") initially rejected the '951 application because, without the XRPD peak values, the

Examiner could not determine that the claims in the '951 patent were patentable over the '090 patent. See id. The Examiner issued a notice of allowance for the '951 patent only after Novo amended its application to include, inter alia, in claims 1 and 2 specific XRPD peak values, the language "having substantially," and the language "peaks obtained with KBr . . . ." See Dkt. No. 8-6 (Letter from Carol E. Rozek, Novo Nordisk of North America, Jan. 25, 1999; Notice of Allowability, Feb. 24, 1999).

C. The '042 Patent[2]

Sun is the holder of U.S. Patent No. 7,667,042 (the "'042 patent"), which was issued on February 23, 2010. The abstract to the '042 patent provides: "Stable polymorphic forms III, IV and substantially amorphous form of an anticonvulsant, tiagabine hydrochloride." Dkt. No. 32-5. The relevant claim in the '042 patent is as follows:

> 2. Polymorph IV of tiagabine hydrochloride that exhibits an X-ray powder diffraction pattern having characteristic peaks expressed in degrees 2 theta at 13.6, 14.5, 15.4, 16.2, 16.8, 23.0, 24.7, 26.0, and exhibits cell parameters as follows: [listing cell parameters].

The '042 patent also references the '951 patent. The specification of the '042 patent states that the '951 patent "claims anhydrous crystalline form of tiagabine hydrochloride referred herein as form II." Id. Thus, in approving the '042 patent, the Examiner necessarily considered that the '042 patent claims a crystalline form of tiagabine HCl – referred to throughout this litigation and this Opinion as "Form IV" – different than the form claimed by the '951 patent.

D. Sun's ANDA and launch of the Sun Tablets

Pursuant to the Hatch-Waxman Act and through a Paragraph IV certification dated April 15, 2005, Sun notified Novo that it had filed ANDA No. 77–555 seeking FDA approval to

[2] The '042 patent is attached to Sun's initial opposition papers as Exhibit J to Declaration of Dr. Peter Stephens. Dkt. 32-5.

market tiagabine HCl tablets in the 2 mg and 4mg dosage strengths. Amend. Compl. at ¶ 8; Dkt. No. 8-3 (Paragraph IV certification). The certification further alleged that claims 1–2 and 4–7 of the '951 patent are not infringed and/or are invalid. See Amend. Compl. at ¶ 18; Dkt. No. 8-3. Sun's ANDA was granted final FDA approval, and, at the time Cephalon filed its Amended Complaint, Sun admitted that it intended to offer for sale the Sun Tablets prior to the expiration of the '951 patent on June 10, 2017, although Sun did not admit to any specific date or timetable.[3] Caraco Answer at ¶ 19. However, by letter dated October 19, 2012, Sun informed the Court and Cephalon that Sun had effected its "at risk launch"[4] of the Sun Tablets the same day. Dkt. No. 158. Following the launch of the Sun Tablets, Cephalon supplemented its motion for a preliminary injunction by adding a request to recall the Sun Tablets.

The Court notes that the Sun API is the actual embodiment of Sun's tiagabine HCl, and according to Sun, the Sun Tablets contain a specified amount of the Sun API that is not significantly altered in the Tablet making process. See Dkt. No. 8-3 (Paragraph IV certification). Throughout the instant litigation, the parties have relied on the Sun API in both experiments and argument to demonstrate the presence or absence of any infringing material in the Sun Tablets. In essence, Cephalon's infringement argument is: the crystalline form in the Sun API matches the crystalline form claimed by the '951 patent, the Sun Tablets necessarily contain some amount of the API, and therefore the Sun Tablets infringe because they contain the same crystalline form as claimed by the '951 patent.

E. SSCI Testing

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[3] Although Sun filed its ANDA in 2005, no action was brought against Sun until 2011, primarily due to Novo and Cephalon's understanding that the Sun Tablets could not be offered for sale until after the expiration of another patent that the Sun Tablets would infringe, which was not due to expire until September 30, 2011. Amend. Compl. at ¶ 19.

[4] "At risk launch" refers to the fact that at the time of Sun's launch, there had been no judicial determination that the Sun Tablets do not infringe on existing patents.

In or around 2006, Cephalon obtained a report of testing data on tiagabine HCl forms from SSCI, Inc. ("SSCI").[5] See Dkt. 136-9 to -10. The SSCI report identified at least twenty different polymorphs of tiagabine HCl, and designated a different letter name to each polymorph, e.g., Form A, Form B, etc. The report also contained data relating to various methods leading to the formation of these different polymorphs. The SSCI data have been relied upon by both parties to supplement their own experimental data. Neither party has directly challenged the reliability of SSCI's method or data, only whether the methods can fairly be compared to the methods of the parties' experts. The Court therefore considers the SSCI data as supplementing, but not supplanting, the parties' own experts and experiments only when the relevance of the data is not significantly disputed.

In that connection, the parties agree that the SSCI report refers to a crystalline form of tiagabine HCl that appears to match the form claimed in Cephalon's '951 patent. During the November hearing, counsel for Cephalon conceded that for all intents and purposes, the SSCI identified "Form B" is the same form claimed in the '951 patent. See Nov. Hearing at 30. On the other hand, despite similarities, Sun has not conceded to Cephalon's recently raised argument that "Form Q" identified by SSCI is the same as Form IV claimed in the '042 patent.[6] See, e.g., Nov. Hearing at 165-68 (Stephens Testimony).

II. STANDARD OF REVIEW

"To obtain a preliminary injunction, a court examines four factors: (1) a reasonable likelihood of success on the merits; (2) irreparable harm if an injunction is not granted; (3) a

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[5] Although unclear, it appears that this testing arose in conjunction with two patent applications filed by Cephalon, U.S. Patent App. Pub. No. 2008/0064727 and U.S. Patent App. Pub. No. 2008/0051435. See Dkt. 32-3 at ¶¶ 24, 26 (Stephens 1st Decl.).

[6] The SSCI data identified "characteristic" peaks for Form Q at 6.4, 11.4, 12.9, 14.8, 15.3, 16.7, 18.8, 22.9, 24.7, 25.3, and additional peaks at, inter alia, 13.5, 13.8, 16.2, and 26.0. Dkt. 135-9 to -10 at 36.

balance of hardships tipping in its favor; and (4) the injunction's favorable impact on the public interest. Although the factors are not applied mechanically, a movant must establish the existence of both of the first two factors to be entitled to a preliminary injunction." Altana Pharma AG v. Teva Pharmaceuticals USA, Inc., 566 F.3d 999, 1005 (Fed. Cir. 2009) (citation omitted) (citing Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1350 (Fed. Cir. 2001)).

In order to demonstrate a likelihood of success on the merits, Cephalon must show that it will likely prove that Sun infringes the '951 patent, and that Cephalon's infringement claim will likely withstand Sun's challenges to the validity of the '951 patent. If Sun raises a substantial question concerning either infringement or validity, i.e., asserts a defense that Cephalon cannot prove lacks substantial merit, the preliminary injunction should not issue. Amazon.com, 239 F.3d at 1350-51 (citation omitted; emphasis added).

These burdens are viewed through the lens of the presumptions and burdens that will inhere at trial. Id. Nevertheless, "[v]alidity challenges can be successful . . . on evidence that would not suffice to support a judgment of invalidity at trial. . . . In resisting a preliminary injunction . . . one need not make out a case of actual invalidity. Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial. The showing of a substantial question as to invalidity thus requires less proof than the clear and convincing showing necessary to establish invalidity itself." Id. at 1358-59 (emphasis added).

"A patent holder seeking a preliminary injunction bears the ultimate burden of establishing a likelihood of success on the merits with respect to the patent's validity. Entegris, Inc. v. Pall Corp., 490 F.3d 1340, 1351 (Fed. Cir. 2007). If the alleged infringer raises a 'substantial question' of invalidity, the preliminary injunction should not issue. Id.; Genentech,

Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1364 (Fed. Cir. 1997). Once the accused infringer satisfies this requirement, the burden shifts to the patentee to show that the defense lacks substantial merit. Entegris, 490 F.3d at 1351." Altana Pharma, 566 F.3d at 1005-1006. Moreover, "[t]he presumption of the patent's validity created by 35 U.S.C. § 282 does not relieve a patentee who moves for a preliminary injunction from carrying the normal burden of demonstrating that it will likely succeed on all disputed liability issues at trial, even when the issue concerns the patent's validity." Helifix Ltd. v. Blok-Lok, Ltd., 208 F.3d 1339, 1351 (Fed. Cir. 2000) (internal quotation marks omitted).

In sum, Cephalon has the burden of demonstrating a likelihood of success on the merits of its infringement claim. Cephalon must demonstrate that it is likely to prove, by a preponderance of the evidence, that Sun's "accused product or method meets every claim limitation either literally or under the doctrine of equivalents."[7] See Pfizer, Inc. v. Teva Pharmaceuticals, USA, Inc., 429 F.3d 1364, 1376 (Fed. Cir. 2005). In contrast, Sun has the burden of raising a substantial question as to the validity of the '951 patent; once Sun has achieved this, the preliminary injunction will not issue unless Cephalon demonstrates that Sun's defense lacks substantial merit. See Entegris, 490 F.3d at 1351.

III. DISCUSSION

A. Cephalon's Infringement Claim

"Determination of patent infringement requires a two-step analysis: (1) the scope of the

[7] The doctrine of equivalents is not, however, being asserted by Cephalon in this motion. In the Amended Complaint, Cephalon alleges generally that the Sun Tablets infringe on "one or more of the claims of the '951 patent, either literally or under the doctrine of equivalents." See Amend. Compl. at ¶ 20. Cephalon later conceded in one of its initial moving papers that "Cephalon is not arguing infringement under the doctrine of equivalents," and has not since attempted to resurrect that argument. Dkt. 47 at 3-4. Thus, the only issue before the Court on this motion is whether the Sun Tablets literally infringe on the '951 patent.

claims must be construed; and (2) the allegedly infringing device must be compared to the construed claims." Novartis Pharmaceuticals Corp. v. Eon Labs Mfg., Inc., 363 F.3d 1306, 1308 (Fed. Cir. 2004).

I begin by looking to the words of the claims themselves to define the scope of the '951 patent, Abbott Laboratories v. Andrx Pharmaceuticals, Inc., 452 F.3d 1331, 1336 (Fed. Cir. 2006), and these words are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art at the time of the filing of the patent application. See, e.g., Medtronic Inc. v. Boston Scientific Corp., 695 F.3d 1266, 1275 (2012) (quoting Phillips v. AWH Corp., 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc). As the Philips court explained:

> In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words. In such circumstances, general purpose dictionaries may be helpful. In many cases that give rise to litigation, however, determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art. Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean. Those sources include the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.

Phillips, 415 F.3d at 1314 (citation omitted; internal quotation marks omitted).

The parties agree that the claims of the '951 patent teach a particular crystalline form of anhydrous tiagabine HCl (the "'951 form" or "'951 crystal"). The parties further agree that the '951 form is characterized by the nine XRPD peaks claimed in the '951 patent – which have been referred to in this litigation as the "characteristic," "identifying," or "diagnostic" peaks of the '951 form – largely because the '951 form exhibits additional XRPD peaks that are shared

with other polymorphs of tiagabine HCl. Beyond this agreement, the parties dispute several construction issues.

Sun argues that the '951 claims must be construed to include the XRPD pattern that is specified in Figure 2 of the '951 patent in addition to the specific XRPD peaks listed in the claims. See Dec. Hearing at 152-157 (Stephens Testimony). Sun buttresses its argument by explaining that XRPD patterns contain more identifying information than the peak numbers do alone – for example, the relative intensities and shapes of the specific peaks can be observed in the pattern. See id. at 156. Cephalon disputes that the '951 claims entail both the XRPD peaks and the pattern from Figure 2, but its argument is undermined by its own expert, Dr. Bugay, who testified several times in deposition that comparison to the '951 patent involves both comparison to the peaks and to the overall pattern. See, e.g., Dkt. No. 136-1 at 249 (Bugay Depo. 7/13/12). Indeed, during the November hearing, Dr. Bugay testified that the Figure 2 "pattern is a description of the three-dimensional structure that's associated with the crystalline anhydrous tiagabine HCl" claimed by the '951 patent. Nov. Hearing at 40-41; see also Dkt. No. 123-1 (Bugay 3d Decl.) ("[T]he '951 patent is directed to anhydrous [tiagabine HCl] having an x-ray powder diffraction ('XRPD') pattern which is shown in Figures 2-8 [of the patent]." (Emphasis added.)). The Court therefore will look to Figure 2 in the same manner as the experts in this case – as being helpful in illustrating a pattern of the XRPD peaks claimed by the '951 patent. See Phillips, 415 F.3d at 1313 (court may look to remainder of patent specification in construing claims).

Sun also contends that Cephalon's claim construction ignores the language "obtained with KBr" in the '951 claims. In support of its construction, Cephalon argues that one of ordinary skill in the art would read the phrase "obtained with KBr" and understand that it was an

obvious error because it does not refer to XRPD analysis but rather to infrared spectroscopic analysis. See Dkt. No. 123 at 5; Nov. Hearing at 46 (Bugay Testimony) (testifying that KBr refers to infrared spectroscopy). According to Cephalon, the Court has the discretion to ignore or correct this "obvious" error in its claim construction. See CBT Flint Partners, LLC v. Return Path, Inc., 654 F.3d 1353, 1358-59 (Fed. Cir. 2011). In response, Sun argues that the proposition set forth in CBT Flint Partners does not apply here because the phrase was not a scrivener's error in the drafting of the claims. Sun points out, correctly, that the language "obtained with KBr" was included after the Examiner rejected the initial application for the '951 patent. See Part II.B.

Sun's argument is superficially persuasive – Novo indeed added the phrase "obtained with KBr" in amending its application. And although Sun has never conceded its argument, the Court notes that Sun has challenged the inclusion of this phrase only collaterally and Sun and its expert, Dr. Stephens, have generally ignored this language when conducting experiments relating to the claims of the '951 patent. Indeed, neither Sun nor Dr. Stephens relied on the language "obtained with KBr" in conducting experiments in this case. Moreover, when Dr. Bugay, Cephalon's expert on infringement, testified that he ignored the phrase, recognizing it as an obvious error, see Nov. Hearing at 43-45, Sun did not raise this issue with its own infringement expert or challenge Dr. Bugay's testimony in this regard on cross-examination. Accordingly, for the purposes of this preliminary injunction motion, and based on the proffered evidence and argument, the Court construes claims 1 and 2 of the '951 patent without regard to the phrase "obtained with KBr." See CBT Flint Partners, 654 F.3d at 1358 ("[I]n deciding whether it had authority to correct a claim, a district court must consider any proposed correction 'from the point of view of one skilled in the art' . . . .").

The parties' remaining claim construction dispute turns on the meaning of the phrase

"having substantially the following [XRPD] peaks." Cephalon argues that an ordinary person skilled in the art at the time would understand this claim language to mean that the XRPD peak values in the '951 patent allow for rounding and inherent experimental error. See Dkt. No. 123 at 6-13. To that end, Cephalon contends that each XRPD peak value claimed by the '951 patent necessarily encompasses the range of XRPD peak values that may be properly rounded to one decimal place. In support, Cephalon relies on several Federal Circuit cases explicitly or implicitly condoning the practice of rounding data. See, e.g., Vikase Corp. v. Am. Nat'l Can Co., 261 F.3d 1316, 1320-22 (Fed. Cir. 2001). Dr. Bugay, Cephalon's expert on infringement, also testified at the November hearing that the '042 patent claims utilized rounding. See Nov. Hearing at 47-49. In addition to incorporating rounding into the '951 claims, Cephalon also argues, with the support of Dr. Bugay's testimony, that the peak values necessarily allow for experimental error – in this case, a margin of error of ± 0.2 degrees two theta.[8] See id. at 53-55. Dr. Bugay explained in his declarations and testimony that the ± 0.2 range was derived from the United States Pharmacopeia ("USP")[9] reference standard. See Nov. Hearing at 52-54.

Sun argues in response that it is inappropriate to apply both rounding and a wide range of experimental error – ± 0.2 rather than ± 0.1 – in this case.[10] Sun argues further that construing the '951 claims to allow for this range of XRPD peak values would render the patent invalid for lack of enablement. See Dkt. No. 135-10 at 14 n.10; Dkt. No. 135-2 at ¶¶ 46-48 (Stephens 3d Decl.). Sun does not directly challenge the use of rounding, but rather contends that when

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[8] Degrees two theta, or º2θ, is the metric used for analyzing results from XRPD testing. See Nov. Hearing at 50-52 (Bugay testimony). All references to XRPD peaks in this opinion are to degrees two theta.

[9] According to Dr. Bugay, and not challenged by Sun, the USP is "a standard setting body for the pharmaceutical industry within the United States," and one of its roles is to give guidance to different techniques, including XRPD analysis. Nov. Hearing at 53.

[10] Sun relies in part on Abbott Laboratories v. Sandoz, Inc., 486 F. Supp. 2d 767, 772-73 (N.D. Ill. 2007) (holding that ± 0.1 range of error appropriate in XRPD analysis).

rounding is used in conjunction with the broad experimental error range relied on by Cephalon and Dr. Bugay, the XRPD peaks claimed by the '951 patent no longer identify peaks characteristic to the '951 form only. Instead, Sun argues that Cephalon's interpretation of the '951 XRPD peaks would include at least six other polymorphs of tiagabine HCl. See Dkt. No. 135-2 at ¶¶ 46-48 (Stephens 3d Decl.).

In that regard, the Court notes that Dr. Bugay initially relied on a range of error of ± 0.1, but has testified since that ± 0.2 is an equally acceptable range of error and should be applied to the facts in this case. Compare Dkt. No. 49 at ¶ 33 (Bugay 1st Decl.) (using ± 0.1 range of error) with Nov. Hearing at 52-55, 94 (Bugay Testimony) (using ± 0.2 range of error). Dr. Bugay's shift appears to correspond to two different theories of infringement advanced by Cephalon. Initially, Dr. Bugay compared the XRPD peaks in Sun's '042 patent to those in the '951 patent and concluded that they all matched within a range of error of ± 0.1. See Dkt. No. 49 at ¶ 40. Cephalon relied on Dr. Bugay's conclusions to argue that Sun's Form IV – which is claimed by Sun's '042 patent and alleged to be present in the Sun API and the Sun Tablets – supported a finding of literal infringement of the '951 patent because of this correspondence of peak values. Dkt. No. 47 at 3-4 ("[T]he XRPD data for Form IV . . . falls within ± 0.1 of all of the nine peaks of claims 1, 2, and 4 when properly rounded to one decimal point. . . . Accordingly, it is clear that Sun's tiagabine hydrochloride Form IV literally falls within the scope of claims 1, 2, and 4 of the '951 patent."). In the most recent permutation of its infringement claim, Cephalon has abandoned the argument that Form IV infringes. Instead, Cephalon argues that the Sun API, and thus the Sun Tablets, are a mixture of polymorphs, one of which is the '951 form. See Dkt. No. 182 at 1-3 (Cephalon closing brief). To support this new argument, Cephalon relies on Dr. Bugay's conclusions identifying the presence of the '951 peaks in the Sun API and the Sun

Tablets within a margin of error of ± 0.2. See Nov. Hearing at 85, 124 (Bugay Testimony); Dkt. No. 123-1 at ¶ 19 (Bugay 3d Decl.).[11] Simply put, Dr. Bugay has submitted four declarations, in addition to testifying at the November hearing, setting forth a constantly evolving theory of infringement. The shifting nature of Dr. Bugay's conclusions causes this Court to view his testimony with some skepticism.

At the same time, Sun's arguments are somewhat undermined by their own patents and the experiments of their own experts. See Dkt. No. 135-2 at ¶ 35 (Jones Decl.) ("I was also asked . . . to determine if any of the observed [XRPD] peaks were within a range of ± 0.2 . . . ."); id. at ¶ 37 (employing rounding); see also The '042 Patent (using both rounded and non-rounded peak values in its claims).

This is not a Markman claim construction proceeding, and the Court need not conclusively determine the proper construction of the claims at this preliminary injunction phase because Cephalon cannot demonstrate a likelihood of success on the issue of infringement under its own proposed interpretation of the claims. See Abbott Laboratories, 544 F.3d 1341 at 1358 ("At the preliminary injunction stage the district court's claim construction is reviewed, as for other legal issues, for the likelihood of correctness of the ruling. This likelihood is based on the underlying facts as found at this stage of the proceedings, recognizing that the burdens at the preliminary injunction stage track the burdens at trial." (Internal quotation marks omitted.)). Even under a broad construction of the XRPD peaks in the '951 patent, Cephalon has not demonstrated that the Sun API contains a form of tigabine HCl that exhibits all nine XRPD

[11] Cephalon's latest infringement argument, presented days before the November hearing, is that the Sun API and the Sun Tablets are a mixture of the '951 form and another form – Sun's Form IV and/or Form Q. As noted supra, Part I.E., there appear to be substantial similarities between Form IV and Form Q, but Sun has not conceded that they are identical forms. See also infra, Footnote 14.

peaks claimed by the '951 patent, and therefore has not demonstrated a likelihood of success on its claim that the Sun Tablets infringe the '951 patent.[12]

Cephalon's infringement argument is two-fold. Cephalon argues first that its expert, Dr. Bugay, has demonstrated that the Sun API contains the same tiagabine HCl form claimed by the '951 patent. Cephalon next argues that Sun's Paragraph IV certification indicates that the tiagabine HCl in the Sun API is present in the Sun Tablets in the same form. Thus, Cephalon contends that it necessarily has carried its burden of demonstrating a likelihood of success in proving that the Sun Tablets infringe based on its showing that the Sun API contains the same anhydrous tiagabine HCl form claimed by the '951 patent. In response, Sun does not dispute the presence of the same form of tiagabine HCl in both the Sun Tablets and the Sun API,[13] but argues that Cephalon has not demonstrated a likelihood of success in proving that the Sun API contains a form of tigabine HCl that matches the '951 form.

Cephalon relies on Dr. Bugay's experiments and analysis of the Sun API and claims that Dr. Bugay has demonstrated that it is more likely than not that the Sun API exhibits the same XRPD peaks and pattern claimed by the '951 patent. See Nov. Hearing at 85, 124 (Bugay testimony); Dkt. No. 123-1 at ¶ 19 (Bugay 3d Decl.) ("[T]he XRPD patterns obtained for the two Sun tiagabine HCl API batches reveals the presence of all nine peaks listed in claims 1 and 2 of the '951 patent within ± 0.2 °2θ."). As noted previously, Cephalon's infringement argument has evolved over the course of this litigation. The most recent permutation of Cephalon's infringement argument – which was fully presented for the first time shortly before the

[12] This is certainly not due to time constraints, as it has been over a year since Cephalon files its Amended Complaint in this action.

[13] Sun, however, points out that that Cephalon has not presented evidence that the XRPD pattern for the Sun API matches the XRPD pattern for the Sun tablets. See Dkt. No. 135-10 at 14 n.9.

November hearing – is that the Sun API and the Sun Tablets are a mixture of the '951 form and another form, namely Sun's Form IV and/or Form Q.[14] Cephalon's reasoning is premised on Dr. Bugay's conclusions that the XRPD peaks exhibited by the Sun API are not fully explained by the presence of Form IV and/or Form Q alone, and thus there must be another form present in the Sun API to account for these additional peaks. Nov. Hearing at 85-84 (Bugay testimony); Dkt. No. 182 at 1 (Sun closing brief). Despite alluding to multiple "peaks" that would identify the '951 form, for the purposes of the preliminary injunction motion Cephalon's "mixture" argument concerns solely XRPD peaks in the Sun API located at 11.3 and 11.4. Nov. Hearing at 94-96 (Bugay testimony) (referencing only peaks at 11.3 and 11.4); Dkt. No. 182 at 1-3 (same). Cephalon argues, based on Dr. Bugay's testimony, that the XRPD peak located at 11.4 in the Sun API correlates to the form claimed by Sun's '042 patent. See Nov. Hearing at 94-95. According to Dr. Bugay, the 11.3 peak, however, is not found in the '042 patent. Id. Instead, Dr. Bugay testified that this peak corresponds to the form claimed by Cephalon's '951 patent. Based on these peaks alone, Dr. Bugay concluded that the Sun API contained a mixture of the '951 form and Form Q and/or Form IV. Id. Cephalon accordingly argues that Dr. Bugay has sufficiently demonstrated, for the purposes of the preliminary injunction motion, the presence of the '951 form in the Sun API, and thus the Sun Tablets. The Court disagrees.

Cephalon's reliance on a single differentiating peak in the Sun API is inadequate to

[14] Prior to the November hearing, Cephalon and Dr. Bugay had stated, in a somewhat perfunctory manner, that the Sun API was a mixture of at least two polymorphs of tiagabine HCl, without identifying the specific polymorphs. See Dkt. No. 153 at 4-6; Dkt. No. 156 at ¶ 3. In response to a request for further clarification, counsel for Cephalon submitted to Sun an interrogatory answer on November 9, 2012, six days before the November hearing date. In that response, counsel for Cephalon stated that it was Dr. Bugay's most recent opinion that the Sun API is more likely than not a mixture of the '951 form and Form IV or Form Q, recognizing that Form IV and Form Q may be the same form. See Dkt. No. 170-5 at 3-4. This was the first time in this litigation that Dr. Bugay opined that the specific make-up of the Sun API was Form IV and/or Form Q, and that these may be the same forms.

demonstrate a likelihood of success on its infringement claim. The Federal Circuit has rejected the notion that literal infringement can be proved on the basis of a single "diagnostic" peak. See, e.g., Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1566 (Fed. Cir. 1997) ("It is elementary patent law that all limitations are material. The single-peak analysis was thus insufficient because . . . in order to prove infringement Glaxo was required to establish the presence of each limitation of the asserted claims." (Citation omitted; emphasis added.)); Zenith Laboratories, Inc. v. Bristol-Myers Squibb Co., 19 F.3d 1418, 1424 (Fed. Cir. 1994) ("[T]he number of lines recited in the claim is 37 . . . [but] 15 of the lines recited in the claim (representing about 40% of the total) were not considered by the [district] court in its comparison. Although the term 'essentially' recited in the claim permits some leeway in the exactness of the comparison with the specified 37 lines of the claim, it does not permit ignoring a substantial number of lines altogether. It is the claim that sets the metes and bounds of the invention entitled to the protection of the patent system."); see also Abbott Laboratories v. Sandoz, Inc., 486 F. Supp. 2d 767, 775 (N.D. Ill. 2007) ("Only four of these seven peaks are within . . . Claim 1. On that basis alone, the plaintiffs' claim of literal infringement fails, because in order for there to be literal infringement, each and every limitation of the claim must be met."). Cephalon has cited no authority to the contrary.

Moreover, this Court previously has faced arguments similar to Cephalon's and found that peaks possibly attributable to more than one form constitute insufficient evidence of infringement. See Roche Palo Alto LLC v. Ranbaxy Laboratories Ltd., CV 06-2003, 2009 WL 3261252, at *37 (D.N.J. Sept. 30, 2009) ("Roche has not presented evidence that additional peaks, at, for, example, 9.5° and 11.8° 2θ, are defining of the crystalline forms of valganciclovir HCl and present in Ranbaxy's tablets. . . . Accordingly, the Court finds that the mere presence of

a peak at 3.5° 2θ alone, as offered here, cannot sustain a finding of infringement because such a peak may be caused by either the crystalline forms X and Y or other possible semi-amorphous forms of valganciclovir HCl like Forms A and B."). Here, the same ambiguity is present. During the November hearing, Dr. Stephens sharply disagreed with Dr. Bugay's conclusion that the 11.3 peak in the Sun API is diagnostic of the '951 form. Rather, Dr. Stephens testified that the 11.3 peak was attributable to Form Q.[15] See Nov. Hearing at 177-78 ("I view the [SSCI] data as quite conclusive evidence that there are two peaks in Form Q that are at 11.3 and 11.4."). Furthermore, Dr. Bugay's own methods of interpreting XRPD peaks and patterns call into question his ability to discern a specific tiagabine HCl form from a single peak. See Dkt. No. 156 at ¶ 34 ("[T]he USP criteria specify that two peaks from two different XRPD patterns can be considered to be equivalent if their peak positions are within ±0.2 °2θ.").

Cephalon's infringement argument and Dr. Bugay's evidence suffer from another fatal flaw. Dr. Bugay testified several times that he compared the Sun API material to material that Dr. Bugay himself generated in accordance with the '951 patent claims and specifications in order to determine whether the Sun API contained the '951 form. In other words, many of Dr. Bugay's conclusions stem from comparisons to his own manufactured '951 material – not from comparisons to the '951 patent claims and XRPD peaks. See, e.g., Nov. Hearing at 94 (Bugay

[15] Cephalon argues in several of its most recent submissions that Dr. Stephens, Sun's expert, has failed to identify the specific polymorphs present in the Sun API. See Dkt. No. 153 at 4-5. The burden, however, is on Cephalon to demonstrate a likelihood of success on proving that the Sun API and the Sun Tablets contain the '951 form, not on Sun to demonstrate which polymorphs are present in the alleged infringing product. See Pfizer, Inc. v. Teva Pharmaceuticals, USA, Inc., 429 F.3d 1364, 1376 (Fed. Cir. 2005). Moreover, to the extent that Cephalon relies on this dispute to raise a concern that the Sun Tablets should not have received FDA approval, that argument is not properly before the Court in a patent infringement action, which the Court noted in the November hearing. See Nov. Hearing at 35-36, 102-103; see also Apotex, Inc. v. Thompson, 347 F.3d 1335, 1343 (Fed. Cir. 2003) (explaining that patent law does not provide any cause of action to challenge FDA regulatory actions).

Testimony) ("For the Sun API . . . this peak table comes from a measurement that I made . . . and then the '951 column here, that refers to my measurement on that '951 material that I made by the example listed in the '951 [patent]." (Emphasis added.)); Dkt. No. 123-1 at ¶ 7 (Bugay Decl. 3d Decl.) ("In order to more easily evaluate and compare XRPD patterns obtained for the various Sun materials, a fresh sample of anhydrous crystalline tiagabine HCl was needed. For this reason, I undertook the preparation of anhydrous crystalline tiagabine HCl according to the procedure in Example 4 described in the '951 patent."). Dr. Bugay arrived at his most recent conclusion that the Sun API, and thus the Sun Tablets, contain a mixture of Form IV from Sun's '042 patent and the '951 form by comparing XRPD data from the Sun API to Dr. Bugay's manufactured sample. See Dkt. No. 123-1 at ¶¶ 20-22. Problematically, however, the XRPD peaks of Dr. Bugay's manufactured sample did not match up exactly with the XRPD peaks claimed by the '951 patent. Only three of the nine XRPD values of Dr. Bugay's sample coincided exactly with the '951 patent; Dr. Bugay had to apply a margin of error of ± 0.1 to the remaining values in order to conclude that his sample was representative of the '951 patent. Dkt. No. 123-1 at ¶¶ 10-12 (Bugay 3d Decl.) (XRPD peak values for Dr. Bugay's sample listed as 6.4, 11.3, 12.9, 13.8, 14.9, 18.6, 19.4, 22.4, and 23.6; XRPD values claimed by '951 patent are 6.4, 11.3, 13.0, 13.9, 15.0, 18.7, 19.4, 22.5, and 23.7). More importantly, this method of comparison has been flatly rejected by the Federal Circuit. "[I]t is error for a court to compare in its infringement analysis the accused product or process with the patentee's commercial embodiment or other version of the product or process; the only proper comparison is with the claims of the patent." Zenith, 19 F.3d at 1423. For these reasons, the Court will not consider this aspect of Dr. Bugay's conclusion that the Sun API form matches the '951 form because that conclusion was arrived at through an improper method of comparison.

Based on the evidence presented – in particular the experts' conflicting testimony and the Court's skeptical view of Dr. Bugay's opinions – the Court determines that Cephalon has failed to demonstrate a likelihood of success on its infringement claim based on the presence of the Sun API in the Sun Tablets. Put differently, Cephalon has not shown, on the evidence submitted to date, that it is more likely than not that Cephalon will be able to prove at trial that the Sun API contains a form of anhydrous tiagabine HCl that infringes on the '951 patent.

The Court addresses two remaining issues concerning Cephalon's infringement claim. First, in addition to not showing a likelihood of success on infringement based on comparison to the Sun API, Cephalon also cannot demonstrate a likelihood of success on infringement based on direct comparison to the Sun Tablets. Dr. Bugay's testing has only identified – at the very most – six of the XRPD peaks claimed by the '951 patent.[16] See Nov. Hearing at 107-111. Cephalon argues that not all nine peaks need to be identified in order to find infringement, and that, as a "matter of science," the Court can infer the presence of the remaining peaks. See Dkt. No. 182 at 6 (Cephalon closing brief). The Court is aware of no authority supporting this proposition, which runs counter to the Federal Circuit's requirement that a finding of literal infringement requires the presence of each and every claim limitation in the alleged infringing product. See,

[16] Dr. Bugay testified that the only reason he could not also identify all nine peaks in the Sun Tablets was due to the high amount of lactose excipient in the Sun Tablets, which obscured the peaks associated with the '951 form. See, e.g., Dkt. No. 156 at ¶ 9 (Bugay 4th Decl.), Nov. Hearing at 122; see also id. at 161-62 (Stephens testimony) ("[W]hat I concluded from the [Sun] tablet data was that the [XRPD] signal was dominated by crystalline excipients that are present in the tablet."). Initially, Dr. Bugay was only able to identify five peaks in the Sun Tablets based on the XRPD data; to identify the sixth peak, Dr. Bugay had to apply a technique called "Fourier Deconvolution." See Dkt. No. 123-1 at ¶¶ 35-38 (Bugay 3d Decl.). Sun's expert, Dr. Stephens, strongly contested the appropriateness of using this technique in this case. See Dkt. No. 135-2 at ¶¶ 21-25 (Stephens 3d Decl.) ("In my opinion, Dr. Bugay's use of Fourier deconvolution to resolve or otherwise enhance his data is not – and has never been – a generally accepted data processing technique to clarify the presence of weak peaks in the presence of strong peaks in XRPD data.").

e.g., Glaxo, Inc., 110 F.3d at 1566. The issue is sharply contested by the parties; the Court declines to infer the additional peaks for the purposes of Cephalon's preliminary injunction based upon the lack of authority for doing so and the Court's somewhat skeptical view of Dr. Bugay's testimony.

Second, the Court notes that Cephalon's proposed broad construction of the '951 claims undermines Cephalon's own infringement argument. Sun Contends that if the XRPD peaks in the '951 claims allow for rounding and an experimental error of ± 0.2, as Cephalon argues, the resulting range for the '951 XRPD peaks would also include the XRPD peaks for at least six other polymorphs of tiagabine HCl.[17] Cephalon rejects this comparison as faulty, explaining that this logic ignores the importance of the type of chemical crystallization process used to create different polymorphs. According to Cephalon's expert, Dr. Bugay, only Form B can result from the specific crystallization process used to create the Sun API. See Dkt. No. 156 at 26-27 (Bugay 4th Decl.). The evidence and argument presented by both sides in this regard is sparse, and the Court cannot make a determination that Cephalon's proposed construction of the '951 claims would necessarily include other polymorphs of tiagabine HCl. However, it is Cephalon's burden at this stage to show a likelihood of success on its infringement claim. This problem of overlapping polymorphs is thus further reason to conclude, for the purposes of the instant preliminary injunction motion, that Cephalon has not demonstrated a likelihood of success on the issue of infringement.

For all these foregoing reasons – i.e., failure to identify matching XRPD peaks and

[17] The XRPD peaks for these other forms are drawn from the SSCI data, and represent peaks that had been identified with respect to those particular polymorphs of tiagabine HCl. See 135-4 (Stephens 3d Decl., Ex. B). When these data are given the same treatment that Cephalon proposes for the '951 XRPD peaks – i.e., rounding and a range of error of ± 0.2 – the data could equally identify either the form claimed by the '951 patent or other polymorphs.

patterns in the Sun API or the Sun Tablets with the '951 claims, reliance on a sample material created by Cephalon's expert instead of the patent claims, and failure to adequately explain overlapping XRPD peak data from other polymorphic forms – the Court determines that Cephalon has not met its burden of demonstrating a likelihood of success on the merits of its infringement claim. Accordingly, on this ground alone, the Court denies Cephalon's motion for a preliminary injunction. See Amazon.com, Inc., 239 F.3d at 1350 ("Our case law and logic both require that a movant cannot be granted a preliminary injunction unless it establishes both of the first two factors, i.e., likelihood of success on the merits and irreparable harm.").[18]

B. Sun's Invalidity Claim

The Court also denies Cephalon's motion for a preliminary injunction because Sun has raised a substantial question as to the validity of the '951 patent, which Cephalon has failed to show lacks substantial merit. See, e.g., Abbott Laboratories v. Andrx Pharmaceuticals, Inc., 452 F.3d 1331, 1347 (Fed. Cir. 2006) (denying preliminary injunction where alleged infringer conceded infringement but raised a substantial question to validity of patent that patentee failed to rebut).

Sun's principle argument, and the one that its expert on invalidity, Dr. Roberts, testified to at the December hearing, concerns the prior art referred to in this litigation as the "McGraw et

[18] The Court therefore does not consider the irreparable harm factor in deciding the instant motion; however, the Court notes that it would appear that Cephalon would likely have demonstrated, in light of Federal Circuit precedent, that the release of a generic product causes irreparable harm to the patent holder. Abbott Laboratories v. Sandoz, Inc., 544 F.3d 1341, 1362 (Fed. Cir. 2008) (citing Purdue Pharma L.P. v. Boehringer Ingelheim GmbH, 237 F.3d 1359, 1368 (Fed. Cir. 2001) (likelihood of price erosion and loss of market position are evidence of irreparable harm); Bio-Technology Gen. Corp. v. Genentech, Inc., 80 F.3d 1553, 1566 (Fed. Cir. 1996) (loss of revenue, goodwill, and research and development support constitute irreparable harm); Polymer Technologies, Inc. v. Bridwell, 103 F.3d 970, 975-76 (Fed. Cir. 1996) (loss of market opportunities cannot be quantified or adequately compensated, and is evidence of irreparable harm)).

al. abstract" ("McGraw"). See Dkt. No. 72 at 15-16. Sun asserts that the anhydrous tiagabine hydrochloride form claimed in the '951 patent can also be formed by following the teachings of McGraw, and thus McGraw inherently anticipates the claims of the '951 patent. Thus, Sun argues, the '951 patent is invalid under 35 U.S.C. § 102(b).[19] See Schering Corp. v. Geneva Pharmaceuticals, 339 F.3d 1373, 1377 (Fed. Cir. 2003) ("A patent is invalid for anticipation if a single prior art reference discloses each and every limitation of the claimed invention.").

Initially, I note that the '951 patent appears to reference the same McGraw publication that Sun relies on in its invalidity argument. See supra Part II.B. According to Cephalon, this reference demonstrates that the Examiner considered and rejected the McGraw publication as anticipating the claims of the '951 patent. See Dkt. No. 123 at 6. However, it appears that the McGraw publication relied on by the Examiner was a summary of the abstract that Sun relies on for its inherent anticipation argument, and thus the Examiner did not base its decision on the same version of the McGraw publication cited by Sun.[20] Compare Dkt. No. 135-1 at Ex. A (full abstract) with Dkt. No. 135-1 at Ex. C (summarized abstract). Cephalon has not challenged this aspect of Sun's argument. Therefore, in analyzing Sun's invalidity arguments, I will focus on the McGraw publication as identified by Sun and set forth here:

> IDENTIFICATION AND CHARACTERIZATION OF POLYMORPHISM IN TIAGABINE HCL BULK DRUG.
> Scott E. McGraw [et al.] . . . .
> Tiagabine is a GABA uptake inhibitor which is being jointly developed by Novo Nordisk and Abbott Laboratories as an anti-epileptic agent. Synthesized as a

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[19] In that connection, there appears to be no dispute in this preliminary injunction motion that if McGraw does inherently anticipate, it would invalidate the patent under § 102 (b) because McGraw was published more than one year before the filing of the '951 patent application.

[20] Sun relies on a McGraw abstract published in the October 1994 supplement of Pharmaceutical Research, at page 150. The abstract relied on by the Examiner appears to be a summary of that abstract, omitting any reference to "hot-stage" XRPD analysis, the significance of which is explained in more detail infra, page 25. See Dkt. 135 at ¶ 14; 135-1.2 (Ex. C to Roberts Decl.). Cephalon does not dispute this difference.

> hydrochloride salt, the compound was observed to crystallize in different polymorphic forms, depending on the conditions of crystallization. The physico-chemical properties of Tiagabine polymorphs were investigated by DSG, TGA, hot-stage X-ray powder diffraction, and moisture sorption experiments. The drug can be reproducibly obtained from water as the Monohydrate crystal form. Upon heating, Monohydrate form loses water to form an unstable Dehydrated Monohydrate crystal. The Dehydrated Monohydrate form can easily be rehydrated by cooling to ambient conditions, or it may be converted to a stable Anhydrous form upon further heating. The stable Anhydrous form can be obtained directly by crystallization from higher alcohols or chloroform. In the solid state, it can only be converted to Monohydrate by equilibrium under very high relative humidities at room temperature. Tiagabine is also capable of forming a Metastable Anhydrous form, which is monotropic with respect to the stable Anhydrous form, and will rearrange its crystal lattice upon heating to produce the stable Anhydrous form.

Sun retained Dr. Richard A. Jones, a professor in chemistry at the University of Texas at Austin, to conduct tests following the teachings of McGraw.[21] Dkt. No. 135-5 (Jones Decl.). For the experiment, Dr. Jones used a sample of tiagabine HCl in monohydrate form obtained directly from the USP. Id. at ¶ 6. Dr. Jones then attempted to replicate the process described in the McGraw publication as a person of ordinary skill in the art would circa 1995, around the time of its publication. Id. at ¶ 11. In particular, Dr. Jones used the "hot-stage" XRPD technique because, in his opinion, it is the best way to study changes in the crystalline form upon heating of the sample. Id. ¶¶ 10-11; accord Dec. Hearing at 26 (Roberts testimony). The hot stage XRPD technique, Dr. Jones explained, involves placing a sample on a heating "stage" in an x-ray diffractometer, adjusting the temperature of the sample, and taking XRPD measurements at a given temperature. See Dkt. No. 135-5 at ¶¶ 10, 13-15. The tiagabine HCl sample was prepared for testing by lightly grinding it and then placing it the XRPD diffractometer. Id. at ¶ 20. In order to replicate the changes to the tiagabine HCl described in McGraw, Dr. Jones collected XRPD pattern data beginning at room temperature and then at subsequent intervals of 20 degrees

[21] Cephalon has not challenged Dr. Jones' qualifications for the purposes of this matter. Cephalon only challenges the methods Dr. Jones employed, as discussed infra in this Opinion.

Celsius, ranging from 50 degrees Celsius to 150 degrees Celsius, by first "up ramping" the temperature by an interval until it reached 150 degrees Celsius, then by "down ramping" the temperature by the same interval until it returned to room temperature. Id. at ¶¶ 22-24. During the heating process, Dr. Jones observed the surface color of the sample change to brown around 90 degrees Celsius, but stated that the color change did not appear to affect the experiment. See id. at ¶ 26. Dr. Jones stored the same sample at room temperature for 30 hours and then collected another set of XRPD data in order to determine whether the sample had remained in stable form after heating and cooling. See id. at ¶ 25.

From the data collected in this experiment, Dr. Jones observed several distinct changes in the tiagabine HCl sample. From room temperature up to 50 degrees Celsius, there was little or no change in the sample's XRPD pattern, but the pattern differed when the temperature was raised to 70 and 90 degrees Celsius. Id. at ¶ 27. The pattern changed further at 110 degrees Celsius but remained the same upon additional heating; this pattern also did not change when the heated sample was cooled, and remained the same after being stored at room temperature for 30 hours. Id. at ¶¶ 28-29.

These observations led Dr. Jones to several conclusions with respect to the McGraw publication, which in his opinion would also be reached by someone of ordinary skill in the art. First, the XRPD data indicated that the USP sample of tiagabine HCl was in its original monohydrate form from room temperature up to about 50 degrees Celsius. Id. at ¶ 30. Second, the data indicated that a new crystalline form occurred between 50 and 70 degrees Celsius, and this new form was unstable upon further heating. Dr. Jones concluded that this form was the "unstable dehydrated monohydrate" described in McGraw. Id. at ¶ 31. Third, the data indicated that the sample turned into another form upon further heating above 90 degrees Celsius, which

did not change form again after cooling. Id. at ¶ 32-32. Dr. Jones concluded that this form was the stable anhydrous form described in the McGraw publication. Id. According to Dr. Jones, no other form other than these three forms was observed at any point during the testing. Id. at ¶ 34.

The final portion of Dr. Jones's experiment was to determine if any of these forms displayed XRPD peaks at 6.4, 11.3, 13.0, 13.9, 15.0, 18.7, 19.4, 22.5, 23.7 º2θ, within a range of ± 0.2. These are the same XRPD peaks claimed by the '951 patent, with the accompanying rounding and experimental error range proposed by Dr. Bugay on behalf of Cephalon. Dr. Jones applied this range of error based solely on Sun's instruction to do so – Dr. Jones was not provided with the '951 patent itself, and was never asked to compare his findings to the '951 patent. Dr. Jones concluded that the stable anhydrous form of the sample had an XRPD pattern that matched the given peak values to within ± 0.1. See id. at ¶ 36-38. (identifying peaks at 6.483, 11.370, 13.832, 14.928, 18.693, 19.474, 22.443, and 23.719).

In connection with Dr. Jones's findings, Sun presented Dr. Roberts at the December hearing as an expert on crystallization science, including characterization by hot-stage XRPD. Dec. Hearing at 6. In reviewing Dr. Jones's data and conclusions, Dr. Roberts confirmed that the McGraw publication taught a method for heating tiagabine HCl to obtain a stable anhydrous form. See Dec. Hearing at 8-11, 26. Dr. Roberts's testimony clarified that the "stable Anhydrous" form referred to in McGraw is a type of crystalline form, not an "amorphous," non-crystalline form. See id. 12-14, 44-45. Dr. Roberts also testified that of the various experimental methods listed in McGraw – "DSG, TGA, hot-stage X-ray powder diffraction, and moisture sorption experiments" – only X-ray powder diffraction allows one to observe the details of a crystalline form, i.e., the polymorph(s). Id. at 14-18. Dr. Roberts further opined that Dr. Jones's methods were consistent with those of ordinary skill in the art at the time of the McGraw

publication. See id. at 26-29 ("[W]hat [Dr.] Jones describes and what is presented [in his experiment] is very much a fairly standard approach to heating material up and recording an X-ray diffraction pattern."); see also Dkt. No. 135 at ¶ 18 (Roberts Decl.) ("Based on my knowledge and expertise in the art, it is my opinion that a person of ordinary skill in the art in the 1995-1996 timeframe, after reading McGraw [] and its disclosure of using hot stage XRPD to analyze tiagabine hydrochloride monohydrate, would have followed and reproduced the disclosures of McGraw [] in at least essentially the same way as Dr. Jones has done."). Significantly, Dr. Roberts testified: "I couldn't see anything in what Dr. Jones did in his attempt to reproduce the teachings of the McGraw publication where any variations would give rise to any different result." See Dec. Hearing at 32; see also Dkt. No. 135 at ¶ 20; id. at ¶ 29 ("[E]ven if there were a question about [Dr. Jones's] analytical procedure, it would take no more than routine experimentation . . . to obtain the anhydrous material claimed by the '951 patent [through the McGraw publication].").

Sun further supplemented Dr. Jones's and Dr. Roberts's conclusions by referencing certain SSCI testing data. Sun identified numerous heating experiments performed by SSCI in which the starting tiagabine HCl monohydrate sample changed into the "Form B" anhydrous tiagabine HCl, i.e., the form having the same XRPD pattern as that claimed in the '951 patent. See Dkt. No. 136-9 to -10 at 5, 19-23 (SSCI reports). Although Sun's experts did not opine directly on this issue, it appears that SSCI did indeed conduct its own heating experiments on tiagabine HCL in monohydrate form and recorded the effects of this heating. The vast majority of these experiments led to conversion of the monohydrate form into the anhydrous Form B when they tracked what would likely be considered normal experimental conditions for heating within the scope of McGraw. See id.

Cephalon rejects Sun's anticipation argument essentially on the ground that McGraw does not "necessarily" and "inevitably" teach the anhydrous crystal form claimed in the '951 patent. See Dkt. No. 153 at 14-15. Cephalon argues that the teachings of McGraw can be practiced in a way that does not yield the claimed characteristics of the '951 patent, and therefore McGraw does not inherently anticipate. Cephalon contends that McGraw does not "expressly disclose" or "provide sufficient experimental details" to inherently anticipate the '951 crystal. Cephalon thus argues that the only way to follow McGraw and create the '951 crystal is to add experimental details that simply are not present in McGraw, e.g., the temperature or duration of heating. In addition, Cephalon also challenges the specific experimental methods of Sun's expert, Dr. Jones. See id. at 19-20 (arguing inter alia that "[o]ne of ordinary skill in the art would not have ground the sample" as Dr. Jones had). Significantly, however, Cephalon has not disputed that the sample created by Dr. Jones – the stable anhydrous tiagabine HCl form[22] – exhibits XRPD peaks that are a near exact match to those claimed by the '951 patent. See, e.g., Dkt. No. 153 at 15-20 (listing Cephalon's challenges to Dr. Jones experiment, none of which includes a challenge to similarity of the material produced to the '951 patent). Thus, for the purposes of Sun's invalidity argument, the Court focuses on the teachings of McGraw and the experimental methods of Dr. Jones.

At the outset, the Court notes that Cephalon has not produced any expert or other evidence that materially calls into question McGraw's teachings, Dr. Jones's experimental methods, or the testimony of Dr. Jones or Dr. Roberts.

Cephalon first argues that McGraw does not inherently anticipate because the publication

[22] This form has been referred to in this litigation as "last sample."

does not expressly disclose the '951 form.[23] Cephalon's argument is misplaced. Sun's claim is that McGraw sufficiently enables one of ordinary skill in the art to create the '951 form, such that this form inevitably flows from the teaching of the prior art – regardless of whether the prior art contains any express disclosure. See Schering Corp. v. Geneva Pharmaceuticals, 339 F.3d 1373 (Fed. Cir. 2003). In Schering, the court explained that Patent law "establishes that a prior art reference which expressly or inherently contains each and every limitation of the claimed subject matter anticipates and invalidates." Id. at 1379 (emphasis added); see also EMI Group N. Am., Inc., v. Cypress Semiconductor Corp., 268 F.3d 1342, 1350 (Fed. Cir. 2001) ("A prior art reference anticipates a patent claim if the reference discloses, either expressly or inherently, all of the limitations of the claim.").[24] Thus, the Court will consider whether Sun has raised a substantial question as to the validity of the '951 patent based on its argument that the McGraw prior art inherently anticipates the creation of the '951 form.[25]

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[23] In that connection, Cephalon also argues that during deposition testimony Dr. Roberts himself described McGraw as a "poorly worded document." Dec. Hearing at 39-43 (Roberts testimony). Dr. Roberts clarified during the December hearing that his deposition testimony referred to the quality of wording in scholarly articles versus industrial abstracts, the latter of which he considered McGraw to be. See id. at 42. Dr. Roberts explained that in his deposition he was not opining on whether McGraw set forth adequate procedures to create the anhydrous tiagabine HCl form. See id. ("I think the message [of McGraw] is fairly clear by someone skilled in the art in 1995.").

[24] Indeed, the cases cited by Cephalon do not require "express disclosure" in order to find that a prior art inherently anticipates. See, e.g., Continental Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991) ("To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.").

[25] The Federal Circuit has set forth several factors a court might consider in determining enablement. See ALZA Corp. v. Andrx Pharmaceuticals, LLC, 603 F.3d 935, 940 (Fed. Cir. 2010) ("In Wands, we set forth the following factors that a court may consider when determining if a disclosure requires undue experimentation: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the

Sun summarizes the import of McGraw as describing the simple heating of tiagabine HCl monohydrate leading to a dehydrated monohydrate and, upon further heating, leading to a stable anhydrous form. Using the teachings of McGraw, Sun argues that its expert, Dr. Jones, created the stable anhydrous form of tiagabine HCl with an XRPD pattern that matches that of the '951 patent; thus, the results of Dr. Jones's experiment are convincing evidence that the stable anhydrous form enabled by McGraw is actually the same form claimed by the '951 patent. In other words, according to Sun, the McGraw publication inherently anticipates the claims of the '951 patent because it "enable[s] someone of ordinary skill in the art at the time to reduce the disclosed invention to practice." See Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1354 (Fed. Cir. 2003). For the reasons stated below, the Court finds that Sun has met its burden of demonstrating that the McGraw publication raises a substantial question as to the validity of the '951 patent.

As already noted, Dr. Jones was able to create the '951 form on what was apparently his first attempt to follow the teachings of McGraw. Additionally, Dr. Roberts explained that he expected the same result to occur in future experiments, in part because the necessary experimental details – which Cephalon argues are "missing" from McGraw – would be known by someone of ordinary skill in the art at the time of the publication. See, e.g., Dec. Hearing at 26-29 (Roberts testimony). Indeed, Dr. Jones was able to recreate the '951 form by reference to the MgGraw publication only; he was never presented with the '951 patent in any form and yet, through McGraw, he was able to recreate the same anhydrous tiagabine HCl form claimed by the '951 patent. Furthermore, even if some amount of experimentation was needed to obtain the

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art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." (Citation omitted.)). I therefore consider Sun's enablement argument and evidence through the lens of these factors.

same results again, Dr. Roberts opined that such experimentation would be routine. See Dkt. No. 135 at ¶ 29. "Enablement is not precluded where a 'reasonable' amount of routine experimentation is required to practice a claimed invention . . . ." ALZA Corp. v. Andrx Pharmaceuticals, LLC, 603 F.3d 935, 940 (Fed. Cir. 2010). Given the results of Dr. Jones's experiment following the teachings of McGraw and Dr. Roberts's testimony, coupled with Cephalon's failure to offer any rebuttal evidence in that regard, the Court determines that Sun has raised a substantial question as to the validity of the '951 patent. The Court further determines that, on this record, Cephalon's argument that McGraw does not provide enough experimental details to enable the creation of the '951 form is insufficient to show that Cephalon's invalidity defense lacks substantial merit.

Moreover, the SSCI data referenced earlier strongly suggests similar results occurred in SSCI's own experimentation on tiagabine HCl. See Dkt. No. 136-9 to -10 (SSCI reports). Like the teachings of McGraw, SSCI apparently conducted numerous experiments that subjected the monohydrate form of tiagabine HCl to increased temperature followed by cooling. In virtually all of these experiments, SSCI observed the formation of Form B, i.e., the '951 form – even under differing amounts and durations of heating the monohydrate form. The only two methods that did not lead to crystallization appear to be so extreme that they would not be considered within the scope of the teachings of McGraw.[26] The data from these SSCI experiments lend

[26] Indeed, these two experiments appeared to involve extreme conditions, namely, a crash cool in a dry ice bath and heating in an oil bath under vacuum followed by ice cooling. See Dkt. No. 136-9 to -10 at 23. Nothing in the McGraw publication suggests these types of heating or cooling conditions and nothing in Dr. Roberts's opinions suggest that these extreme conditions constitute normal experimental conditions for hot-stage XRPD analysis. Inherent anticipation based on a prior art publication includes only normal and usual methods, and does not include unusual techniques. See, e.g., Perricone v. Medicis Pharmaceutical Corp., 432 F.3d 1368, 1383 (Fed. Cir. 2005) (citing In re King, 801 F.2d 1234, 1236 (Fed. Cir. 1986). Accordingly, I find Cephalon's reliance on these two outliers to be misplaced.

further credence to Sun's argument that McGraw inherently anticipates the '951 patent claims, and thus further support this Court's determination, in light of the evidence before it, that Sun has raised a substantial question as to the '951 patent's validity. Again, Cephalon has failed to offer any convincing evidence or argument to rebut Sun's defense. Cf. Glaxo Inc. v. Novopharm Ltd., 52 F.3d 1043, 1047 (Fed. Cir. 1995) (affirming district court's rejection of defendant's anticipation defense where both sides offered evidence that the prior art could yield more than one polymorph).

Cephalon's remaining challenges to Dr. Jones's experimentation methods are also unavailing. Cephalon argues that Dr. Jones's experiment, and thus its result, was flawed because (1) the purity of the starting sample of tiagabine HCl was unknown, (2) the starting sample was ground, which can affect crystallization, and (3) the sample browned during heating. None of these arguments demonstrate that Sun's invalidity argument with regard to McGraw lacks substantial merit.

Dr. Jones stated that he obtained the starting sample for his experiment from the USP. Dkt. No. 135-5 ¶ 6 (Jones Decl.). In the instant litigation, both Cephalon and Sun have relied on USP data and material. During the November and December hearings, both Dr. Bugay and Dr. Roberts explained the role of the USP, with Dr. Bugay testifying that the USP is a "standard setting body for the pharmaceutical industry within the United States," and that it maintains reference information of the specifications of drugs in its catalog. See Nov. Hearing at 53. Dr. Roberts further testified that although he did not examine the USP reference material used by Dr. Jones, he expected it to be the USP's usual grade of material.[27] See Dec. Hearing at 34-35.

[27] Dr. Jones attached as an exhibit to his declaration a photo of the USP packaging for the sample. See 135-6 at Ex. C. The packaging is labeled as a "reference sample." Dr. Roberts appears to base his opinion regarding the purity of Dr. Jones's sample in part on this packaging.

Thus, although Sun's experts could not definitively confirm the purity of the sample used in Dr. Jones's experiment, the Court finds that the fact that this sample was obtained from the USP is sufficient to conclude that the sample was appropriately pure for testing purposes. Indeed, Cephalon presented no evidence to suggest otherwise.

Dr. Jones also stated that he "lightly ground" the starting sample prior to the hot-stage XRPD testing. Dkt. No. 135-5 at ¶ 20 (Jones Decl.). Cephalon contends that grinding can affect polymorph formation, and thus the Court cannot be certain that the same form would have resulted from Dr. Jones's experiment had he not ground the sample. In support, Cephalon did provide an excerpt from a scientific publication stating "polymorphic transformations have been observed to occur on grinding of certain materials." Dec. Hearing at 48 (Roberts testimony). Dr. Roberts agreed that grinding may affect the outcome of a procedure when, for example, the grinding is in the nature of "high impact milling . . . where a substantial amount of mechanical work would be done on the powder." Id. at 37. Nevertheless, Dr. Roberts testified that Dr. Jones did not subject the starting sample to a substantial amount of grinding, and thus, in Dr. Roberts's opinion, this was not a case where the sample would be affected by the grinding. See id. Based on this evidence, the Court finds that the light grinding of the sample likely did not affect the outcome of Dr. Jones's experiment.[28]

Cephalon's remaining contention is not even an argument. Cephalon merely points out that Dr. Jones observed the sample turn brown when the temperature began to exceed 90 degrees Celsius. See id. at ¶ 26. Yet Dr. Jones already stated that this color change did not appear to have an effect on the experiment, see id., and Cephalon has provided no argument, let alone

[28] The Court notes that Dr Bugay prepared his own samples of tiagabine HCl by converting them to powder form by applying pressure using a mortar and pestle. See Dkt. No. 123-1 at ¶ 32 (Bugay 3d Decl.).

evidence, that suggests that browning would affect the outcome of the experiment. The Court finds that the issue of browning does not change the result here.

Considering the foregoing evidence, the Court determines that Sun has raised a substantial question as to the validity of the '951 patent. Dr. Jones and Dr. Roberts have demonstrated that the McGraw publication can be relied on, using normal experimental conditions and techniques, to create the same anhydrous tiagabine HCl form claimed in the '951 patent. Cephalon's challenges are not convincing and go against the weight of the evidence. In sum, Sun proffered three experts[29] with regard to the McGraw publication and Dr. Jones's results, while Cephalon has proffered none. Thus, for the purposes of this motion for a preliminary injunction, I conclude that Sun has raised a substantial question to the validity of the '951 patent based on the McGraw publication as a prior art that inherently anticipates. Furthermore, Cephalon has failed to show Sun's invalidity defense lacks substantial merit. Accordingly, on this additional basis, the Court concludes that Cephalon has not sustained its burden for a preliminary injunction. See Altana Pharma, 566 F.3d at 1006.

IV. CONCLUSION

In sum, under the burdens applicable to a preliminary injunction, the Court concludes that Cephalon has not demonstrated a likelihood of success on its claim that the Sun Tablets infringe claims 1 and 2 of the '951 patent.[30] The Court also concludes that Sun has raised a substantial

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[29] Dr. Stephens testified at the November hearing that out of all the samples he has looked at in conjunction with this litigation, Dr. Jones's sample 'is the closest numerical match to the claims of the '951 patent." Nov. Hearing at 185-87.

[30] Initially, Cephalon also argued that the Sun Tablets infringe on claim 4 of the '951 patent, but in its most recent papers and argument, Cephalon has not appeared to continued to pursue that claim. Claim 4 is not an independent claim, but rather is dependent on claim 1. Because I have already concluded that Cephalon has not carried its burden of demonstrating a likelihood of success as to claim 1, to the extent that Cephalon basis its motion for preliminary injunction on Sun's infringement of claim 4, that argument necessarily fails as well. See, e.g.,

question regarding the validity of the '951 patent in light of the likelihood that the McGraw publication inherently anticipates the claims of the '951 patent, and Cephalon has not shown that Sun's argument lacks substantial merit.

For these foregoing reasons, Plaintiff's motion for preliminary injunctive relief is **DENIED**.

An order will be entered consistent with this Opinion.

Dated: December 20, 2012

/s/ Freda L. Wolfson
Freda L. Wolfson, U.S.D.J.

Wahpeton Canvas Co. v. Frontier, Inc., 870 F.2d 1546, 1553 (Fed. Cir. 1989).